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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/551,218	07/24/2006	Marie-Noelle Bizot	PA/4-32908A	4236

1095 7590 09/27/2007

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CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 104/3
EAST HANOVER, NJ 07936-1080

EXAMINER	
EBRAHIM, NABILA G	

ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
09/27/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/551,218	BIZOT ET AL.	
	Examiner	Art Unit	
	Nabila G. Ebrahim	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-15 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-15 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 09/27/2005.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The receipt of Information Disclosure Statement dated 9/27/05 is acknowledged.

Information Disclosure Statement

1. The information disclosure statement filed 09/27/2005 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 1-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims recite "a mixture in a divided form" the specification does not clearly define the meaning of a divided form and the phrase renders the claims ambiguous.

2. Claims 2-4 are under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims recite "a dissolution characteristic in water is more than about ...% after 30 minutes", it is not clear if this dissolution rate is in vitro before

administering the drug to a subject or it is the dissolution rate in vivo after administering the drug.

3. Claims 5-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. the claims recite a "the oral suspension of claim 1; wherein said mixture in divided form is a crushed tablet" it is not clear how a suspension can be a crushed tablet without a liquid.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over DE BRUIJN et al. WO0010526 (De Bruijn) in view of Patel et al. US 20030180352 (Patel) and further in view of Achong et al. US 20040162273 (Achong).

De Bruijn teaches a pharmaceutical composition, in particular to a composition for administering active agents which are poorly soluble in aqueous media, and/or which are acid sensitive (abstract). The composition comprises tegaserod (pages 5, and 7) or its salt (page 5) and is prepared to have a dissolution in water of about 30%-90% in 5 minutes (page 7), this rate reads on the recitation of instant claim 4. The reference also discloses a dissolution rate of 95% -100% in 30 minutes (page 8), the rate is close to the recitation of instant claims 2 and 3. note that using "about" makes the rates probably closer. In addition, it is expected that people skilled in the art are able to adjust dissolution rates by changing different ingredients in a dosage form. The composition could be in the form of tablets or capsules, or parenterally, e. g., in the form of injectable solutions or suspensions or in a suppository form (page 13). The compositions of the invention were packed in conventional manner to keep out humidity, e.g., in a blister pack, optionally with a desiccant (page 17). Regarding claims 8 and 9 that recite

amount of tegaserod in the dosage form an amount of 6mg or 2 mg, De Bruijn teaches that a tablet may have different amounts according to the condition it is used for, for example for irritable bower syndrome (IBS), 1 mg to 12 mg of active agent is used in the tablet (page 9).

Claims 5-9 recited "a crushed tablet" which reads on a chewable tablet, powder, granulate, bead etc. comprising the tegaserod.

De Bruijn does not teach a crushed tablet or beverage.

Patel teaches solid carriers for improved delivery of active ingredients in pharmaceutical compositions. The composition is meant to mask the taste of unpalatable pharmaceutical active ingredients [0028]. Patel suggests making the active agent of the unpalatable drugs among which is tegaserod [0058] and the dosage form can be a powder or a multiparticulate, such as a granule, a pellet, a bead, a spherule, a beadlet, a microcapsule, a millisphere, a nanocapsule, a nano sphere, a micro sphere, a platelet, a minitablet, a tablet or a capsule [0229]. The composition of the invention can be administered as a chewable tablet, a quick or fast dissolving tablet, an effervescent tablet, a buccal or sublingual solid, a granule, a film, a sprinkle, a pellet, a bead, a pill, a powder, a triturate, a platelet, a strip or a sachet. Compositions can also be administered as"dry syrup", where the finished dosage form is placed directly on the tongue and swallowed or followed with a drink or beverage ([0272], see also claims 24 and 47). The use of water as a beverage is conventional type of a beverage that is usually known and used by the public.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine Patel to De Bruijn because Patel teaches a way for masking the unpleasant taste for the drugs disclosed.

Neither of the references disclosed apple juice as a beverage with the tegaserod.

Achong teaches powder pharmaceutical composition. The reference discloses that powder pharmaceutical compositions can also be formulated to contain aesthetically pleasing flavor and sweetener ingredients [0008]. when the powder pharmaceutical compositions can be dissolved in a liquid, a such as cold water, ice tea, orange juice, grape juice, and apple juice [0028].

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine Achong to the invention of De Bruijn and Patel and use apple juice as Achong teaches because the reference discloses that apple juice is an aesthetically pleasing flavor. The expected result would be a composition comprising tegaserod or a pharmaceutically acceptable salt swallowed by the use of a beverage or added to a beverage such as water or apple juice.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nabila G. Ebrahim whose telephone number is 571-272-8151. The examiner can normally be reached on 8:00AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Nabila Ebrahim
9/9/07

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER